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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,270	01/22/2002	Edward P. Perez	7404-318	6329

7590 04/06/2004

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EXAMINER

DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,270

Applicant(s)

PEREZ ET AL.

Examiner

D. Jacob Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5, 13, 14, 22-28, 32-36 and 44-77 is/are pending in the application.
- 4a) Of the above claim(s) 24-28, 34 and 73-77 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5, 32, 33, 35, 36, 44 and 54-72 is/are allowed.
- 6) ☒ Claim(s) 13, 14, 22, 23, 47 and 49-53 is/are rejected.
- 7) ☒ Claim(s) 45, 46 and 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/24/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 23 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. (US 5,951,492). Douglas discloses a device for sampling body fluid (Figs. 1-4) comprising a main body 18 defining a capillary channel, a lancet 14, an annular space 36 between the lancet and main body. As illustrated in Figs. 1 and 2, the lancet is advancable and retractable. The device further comprises a test element/testing means 30 (Fig. 3) in communication with the annular space. A retraction mechanism/spring 28 retracts the lancet.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burns (US 4,375,815) in view of Douglas '492. Burns discloses a lancet device comprising a main body 12, a lancet 18, a biasing means/spring 21 mounted within the annular space between the lancet and main body, and a bearing surface.

Burns fails to disclose that the main body is a capillary tube. Nevertheless, Douglas teaches a main body sized to be a capillary tube to draw and maintain blood. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Burns main housing such that it is sized to be a capillary tube in order to draw and maintain blood.

Burns also fails to disclose a testing element in communication with the annular space. Nevertheless, Douglas discloses a testing element 60 in communication with an annular space in order to test blood. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a test element in communication with the annular space to Burns' device in order to test blood.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burns in view of Douglas '492, and in further view of Thorne et al. (US 5,776,157). Burns discloses that the needle may be made of steel, but the patent is silent regarding the specific type of steel. Nevertheless, Thorne teaches a lancet device with a spring, wherein the spring is made of stainless steel, because it is resilient and biocompatible. Therefore, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to the steel spring out of stainless steel, because stainless steel is resilient and biocompatible.

Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas '492. Douglas is silent regarding the space between the lancet and main body being between 20 and 200 micrometers. Nevertheless, Douglas does disclose a capillary tube, which must be changes in the size of a component involve merely routine skill in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make Douglas' annular space between 20 and 200 micrometers.

Claims 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas '492 in view of Tezuka et al. (US 5,569,287). Douglas is silent about a hydrophilic lancet or a hydrophilic coated lancet. Nevertheless, Tezuka teaches a hydrophilic lancet and a lancet coated with a hydrophilic material (Col. 3 line 66 – col. 4, line 16) to attract and collect the blood. The Douglas device is likewise intended to attract and collect blood. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to either make the Douglas lancet out of a hydrophilic material or to coat the device with a hydrophilic material, as taught by Tezuka, in order to attract and collect blood.

The interior of the Tezuka needle is used to attract and collect blood, which is similar in function to the interior of Douglas' main body 18. Tezuka teaches that the

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interior surface of the needle is hydrophilic to attract and collect blood. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the interior surface of Douglas' main body 18 out of a hydrophilic material to attract and collect blood.

Allowable Subject Matter

Claims 5, 32, 33, 35, 36, 44 and 54-72 are allowed. The prior art fails to disclose or suggest all of the limitations of claim 5 including, "said test strip is radially mounted around said lancet." The prior art fails to disclose or suggest all of the limitations of claim 32 including, "retracting said lance into said capillary channel." The prior art fails to disclose or suggest all of the limitations of claim 44 including, "a lancet slidably received in the body to lance an incision."

Claims 45, 46 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

In response to the amendment received February 24, 2004, new grounds of rejection have been made in view of new prior art.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD
March 20, 2004


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700